Responses to USEPA Comments on the Draft Problem Formulation Document
February 28, 2013

Comment No.	Section, Page No., Paragraph	Comment	Response
1.	General Organization	The Problem Formulation Document (PFD) and the associated eight-step process is focused on Ecological Risk Assessment (ERA); therefore the document should be better organized to accommodate the inclusion of elements for the Human Health Risk Assessment (HHRA). Reorganization of the document should include Section 6, Page 6-1, "Next Steps," to break out the information into ecological and human health subsections. The Introduction states that the PFD was prepared "to establish the overall goals, breadth, and focus of the baseline ecological and human health risk assessment;" however, the document is not organized in its presentation or clear in its discussion of each of these elements. Please provide additional text to create a linkage between goals, risk assessment elements, and data needs.	The organization of the document follows the outline agreed-to by Tierra, EPA, and the Partner Agencies (refer to Final Outline dated 3/15/12). No change to the PFD is planned as a result of this comment.
2.	Ecotoxicity Profiles	The ecotoxicity profiles present a very generic overview of ecological hazards and likely toxicological effects associated with the different groups of chemicals of potential ecological concern (COPECs). This generality provides only limited heuristic value in identifying specific data needs, establishing data quality objectives (DQOs), and preparing the Field Sampling Plan (FSP). Please revise the ecotoxicity profiles to include relevant information for FSP development, such as the much greater sensitivity of many life forms to specific contaminants, especially PCBs and dioxins.	As agreed-to during the 1/22/13 call with EPA, the requested information will be incorporated into future risk assessment documents (e.g., sampling plans, BERA report).
3.	Lack of Focus on Sensitive Life Stages	Sensitive life stages were not taken into consideration when defining important factors for selecting representative receptor species (pp. 4-14 and 4-15) or as a basis for discussion in the ecotoxicological profiles (see General Comment No. 2 above). This information is critical to designing a FSP and collecting appropriate data necessary to conservatively estimate ecological risks. Sensitive life stages for each representative ecological receptor category should be identified for all contaminant groups so that the proper Measurement Endpoints and Measures of Effect can be considered in the selection process.	As agreed-to during the 1/22/13 call with EPA, the requested information will be incorporated into future risk assessment documents (e.g., sampling plans, BERA report).

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4.	Ecological Risk Assessment Data Needs	The understanding of ecological risk assessment data needs necessary to develop an efficient FSP has not advanced materially since the June 2011 Workshop. Selected examples are provided below and require elaboration in the revised document: The rationale for suggesting that two vertical water column strata be sampled is not clear (is it important to obtain a representative range of exposure concentrations from typical water column to elevated epi-benthic, or are two different habitat zones the focus, such as in the channels). The document doesn't provide the basic discussion so that the reader can understand the rationale. Why are polychaetes worms and other soft-bodied benthic organisms not included in the list of whole body invertebrates? It is not clear how data on "egg, feather, or blood tissue from birds" may be used in the BERA and why these data are important and represent a data need. Please revise the document to further clarify the data need and its use in the Baseline ERA (BERA).	The rationale for sampling different water column depths (epibenthic vs. water-column exposure) will be provided. Polychaete worms (*Neanthes virens*) are discussed on page 4-16 and in Table 4-3. The data needs for avian egg tissue will be clarified.
5.	Background and Reference Data	The document states that background and reference data will be used as part of the Remedial Investigation (RI); however, the terms are not defined and their use in the RI and in the risk assessments in particular is unclear. Please provide detail on how background and reference data will be established for the Newark Bay Study Area (NBSA) and used in the risk assessments. Please also define the terms "background" and "reference area".	The terms "background" and "reference area" will be defined in the document. Future work/sampling plans will provide details such as proposed sampling areas for background and reference locations and how data collected from these areas will be used in the risk assessments.
6.	Modeling	The document lacks a discussion of modeling and how it will be incorporated into the risk assessments (RAs). Further detail on how the Passaic River/Newark Bay hydrodynamic model, sediment transport and chemical fate and transport model will be used to support the RAs, along with discussions of other proposed modeling activities, would be very helpful to furthering EPA's understanding of Tierra's proposed ERA process. Please note the CPG will be completing a bioaccumulation model for the LPRSA and the NBSA as part of the LPRSA RI/FS, as required by the AOC.	Specific details about hydrodynamic modeling, sediment transport, and chemical fate and transport will be described in upcoming work plans/sampling plans and the revised CSM.

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7.	Pathways Analysis Report	The document should clarify that a Pathways Analysis Report (PAR) will be submitted for EPA review and approval before the risk assessment is developed.	Text will be added as suggested.
8.	RME and CTE	The document should also clarify that the assessment will be conducted for the Reasonably Maximally Exposed (RME) individual and the Central Tendency Exposed (CTE) individual consistent with EPA guidance for Superfund.	Clarification will be made that the HHRA will be conducted for RME and CTE scenarios, per EPA guidance.
9.	Next Steps	Please discuss in Section 6, "Next Steps," how project activities will be coordinated to facilitate a late summer/early fall 2013 data collection start.	Following approval of this PFD, the next step would be the development of work plans/field sampling plans, and QAPPs. All of these need to be approved prior to implementation of the field program. Therefore, it is premature to commit, in writing, to a projected start date for data collection.
10.	Section 1, Introduction, Page 1-1.	Please add a statement to the Introduction that the problem formulation will define the questions that need to be addressed during the BERA and the HHRA.	A statement will be added to the Introduction stating that one of the purposes of the document will be to define the questions that need to be addressed during the BERA and the BHHRA.
11.	Section 1, Introduction, Page 1-1, last paragraph.	The bulleted list of guidance documents pertains to ERA. The planning and scoping phase within the HHRA process does not include a formalized "problem formulation" step analogous to Step 3 of the ERAGS guidance; therefore, please add an explanation of the intent of the PFD document for the HHRA and what guidance was followed to present the HHRA information (to clarify the document organization for a wider readership). Please also add a reference to Section 1.2, where the HHRA guidance is mentioned.	Tierra recognizes that a PFD is not typically part of the HHRA process. Per the response to Comment 175, text to explain the PFD concept for HHRA will be added to the Introduction.
12.	Section 1, Introduction, Page 1-1, last paragraph.	The BHHERA Workshop held in June 2011 should be listed as a primary basis for the document.	While the BHHERA Workshop is not a primary basis for the Problem Formulation (CERCLA guidance is), the BHHERA Workshop and its associated meeting minutes will be referenced.
13.	Section 1.1.1, ERA, Page 1-2, First paragraph.	Describing the SLERA as "highly conservative" and the results as "highly uncertain" seems to call into question the validity of the SLERA and should be stricken from the document.	Text will be edited as suggested.

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14.	Section 1.1.2, HHRA, Page 1-3.	As discussed at the June 28/29, 2011 workshop, use of a probabilistic risk assessment will require a separate work plan. Please add submittal and approval of a PRA Work Plan to the discussion of the potential probabilistic risk assessment. Also, the PRA will be based on exposure assessments and not toxicity. In addition, the reference should also include EPA's policies regarding PRA referenced in the 1997 Policy on the Use of Probabilistic Risk Analysis available at: http://www.epa.gov/spc/pdfs/probpol.pdf and subsequent documents regarding PRA.	References to the PRA Work Plan and EPA's 1997 PRA Policy will be added.
15.	Section 1.1.2, HHRA, Page 1-3.	The RAGS guidance documents cited as references for conduct of the baseline HHRA are incomplete. For example, RAGS Parts B, C, E, and F are not included. Please add a reference to the full set of RAGS guidance documents pertinent to preparation of the BHHRA.	Citations for the additional RAGS documents will be added.
16.	Section 1.1.2, HHRA, Page 1-3.	The list of EPA guidance documents should be expanded to include EPA guidance, policies and guidance that are available at www.epa.gov/risk and the specific guidance from Superfund available at: http://www.epa.gov/oswer/riskassessment/risk_superfund.htm.	Citations for the EPA websites and associated documents will be added.
17.	Section 1.1.2, HHRA, Page 1-3.	The PFD states that the baseline HRRA will be conducted following "a two-tiered approach designed to support risk management decision-making by initially defining the constituents of potential concern (COPCs) for each medium, based on existing and new data collected during the RI, and using this information to prioritize areas requiring further assessment." The two-tiered approach is not discussed in further detail in Section 5 of the document (BHHRA). A more complete description of the two-tiered approach should be added to the document to clarify its purpose and how it will be used to prioritize areas for further assessment.	The reference to a two-tiered approach will be removed.

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18.	Section 2.1, History, Page 2-1.	This section needs to be revised to include a more detailed description of the sources and releases of contaminants to the NBSA. In particular, the Diamond Alkali Superfund Site and the known transport of contaminants from this site into the NBSA should be discussed in this section. Please add a discussion of the Diamond Alkali site and the establishment of the Newark Bay Superfund Site as an operable unit of the Diamond Alkali site. Releases of hazardous substances into Newark Bay are generically described. It would be helpful to clarify that releases directly into Newark Bay and also into its tributaries are both expected to have impacted sediment and water quality in the Bay.	Additional details regarding sources are unnecessary for the purposes of this document. Please refer to other RI reports for additional detailed information (e.g., CSM).
19.	Section 2.2.1, Geographic Areas, Page 2-3.	Please expand the discussion in Section 2.2.1 to address habitat types and area usage by receptors. The BERA should be based upon habitat types and area usage by the selected receptors, as opposed to strict geographic boundaries. The RI, conversely, should focus on nature and extent of contamination, which may be geographical in nature.	As discussed at the BHHERA workshop (refer to BHHERA Workshop Meeting Minutes dated December 1, 2011), the Bay will be divided into geographic regions to be consistent with the divisions in the SLERA.
20.	Section 2.2.1, Geographic Areas, Page 2-3.	Please delete the last sentence of Section 2.2.1 that states that the entirety of the tidal straits will not be evaluated.	It is important to point out that, while portions of the associated waterways will be evaluated, the boundaries of the NBSA established in previous work plans do not include the entire length of the Kills. Consistent with what Tierra has done in the past, investigations will continue beyond the currently defined boundaries of the NBSA but it is not anticipated that the whole of the Arthur Kill or Kill van Kull will be evaluated.
21.	Section 2.2.2, Geomorphic Areas, Pages 2-3 through 2-7.	Geomorphic areas only add up to 87% of the bay area as described in Sections 2.2.2.1 through 2.2.2.5. In addition, some of the geomorphic areas share attributes with other areas. For example, the intertidal areas and the industrial shoreline are really the same type of area within the bay. In addition to geomorphic areas, the bay should be presented by habitat type. Please correct/clarify the area percentages, as appropriate.	Geomorphic area percentages will be confirmed. The intertidal areas and industrial shoreline are different areas of the Bay – Figure 2-4 will be updated to reflect this distinction and eliminate overlap. The Bay is presented by habitat type starting in Section 3.1.1.1.

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22.	Section 2.2.2.1, Subtidal Flats, Page 2-5.	The document states the term 'Subtidal Flats' will be used to represent both the Subtidal Flats and Historically Disturbed Subtidal Flats. Combining these areas into one term could result in a loss of important differences between the two areas (i.e., depth and maximum level of contamination in relation to the surface) that could underestimate actual risk. For this reason, these areas should be assessed separately.	A distinction between the subtidal flats and historically disturbed subtidal flats is not important in terms of sampling for the risk assessment, which will only consist of the top 6 inches of sediment. Furthermore, ecological or human receptors in these areas cannot differentiate between the two areas. A description that distinguishes these areas in terms of depth and maximum COPEC concentrations is provided in other RI documents (e.g., DEAR).
23.	Section 2.2.2.3, Channels, Page 2-5, First Paragraph, Fourth sentence.	This sentence states that the HDP is deepening channels North of Port Newark to the mouths of the Passaic and Hackensack, which is erroneous. Apart from the channel south of Shooter's Island, the HDP is deepening the channels SOUTH of (and not including) Port Newark Channel.	The text will be corrected to discuss the portions of the Bay located South of Port Newark.
24.	Section 2.2.2.3, Channels, Page 2-6, Second paragraph.	As previously commented by the Corps, the RI line drawn separating Port Channels from Navigation Channels is arbitrary and somewhat misleading. For example, much of the area described as "Port Channels" are in fact federal navigation channels, which have largely undergone federal channel deepening [Port Newark Channel in 1989-1994, and Port Elizabeth and South Elizabeth Channels in 1989-1994 (35' to 40' MLW navigable depth), 1999-2004 (40' to 45') and now 2004-2012 (45' to 50')]. The Port Channels, as well as the navigation channels (notably those at Port Newark through the southern half of the NBSA, excluding the channel south of Shooter's Island), have been deepened such that no historical sediment deposits presently reside in these areas and these areas (both Port and Navigation Channels) require regular maintenance dredging (not just the Port Channels, as the text states). Please revise the text accordingly.	The text will be revised to clarify that both Port and Navigation Channels require regular maintenance dredging.
25.	Section 2.2.2.3, Channels, Page 2-6, 3rd Paragraph, second line.	Please replace "verses" with "versus."	Edit will be made as suggested.

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26.	Section 2.2.2.5, Industrial Waterfront Area, Page 2-7, and Figure 2-4.	Clarification is needed for the statement "shoreline areas along the NBSA within 100 ft. of the entire shoreline of the NBSA, excluding Intertidal Areas, are considered part of the Industrial Waterfront Area". Review of Figure 2-4 indicates that the entire NBSA shoreline is categorized as the geomorphic area Industrial Waterfront, which is potentially misleading with regard to important non-industrial zoning and land use in some areas of NBSA. If overlap is implied, this should be more clearly described in the text and then depicted by superimposing residential, recreational (including public walkways and docks), and open space areas on Figure 2-4.	Please refer to the EPA-approved NBSA Phase I Work Plan (Section 3.1.2.6) which identified the 100-ft boundary from shoreline as "Industrial Waterfront Area" for purposes of the NBSA Phase I Investigation. This was similarly carried over to Phase II and subsequent nature and extent-related reports for the RI program (e.g., DEAR, Deposition Report). The PFD is consistent with the existing terminology. Figure 2-4 will be revised such that the Industrial Waterfront Area does not overlap with the Intertidal areas.
27.	Section 2.2.2.5 Industrial Waterfront Area, Page 2-7.	The purpose of defining this particular geomorphic unit, which appears to be a subset of the intertidal/subtidal zone, is not clear. A brief discussion of the need for this segregation should be provided at the beginning of this section.	The Industrial Waterfront Area has been identified and described in detail in other Tierra RI-related documents (e.g., Interim CSM, Phase II RIWP, DEAR). It is a sub-section of the subtidal area and the port channels, but does not include the intertidal zone. A full discussion of the rationale and segregation of this area within this document is not necessary for the purposes of the risk assessment.
28.	Section 2.2.3, Tributaries, Page 2-7, 2nd Paragraph, 7th line.	Replace "consists of" with "includes" (Note: 34 square miles >> 8,400 acres).	Edit will be made as suggested.
29.	Section 3.1, Qualitative Data, Page 3-1.	The document would be improved and would help EPA's understanding by specifically describing how the quantitative data that are described will be used in the BERA and HHRA (e.g., to support the updated COPEC screen, to assess risks to ecological receptors, to assess risks to human health, etc.).	A description stating how the quantitative data will be used in the risk assessments will be added.
30.	Section 3.1.1, Land Use and Important Ecological Habitats, Page 3-1.	Missing from this section is the category of residential use that is contained within the concept of "urban landscape". Land categorization per Anderson et al. (1976) is not synonymous with "land use" in the typical use of this term for risk assessment, and is therefore confusing in this section. The term 'habitat' is recommended in place of 'land use'.	Residential land use is not included in these land use categories identified by the State of New Jersey. These broad land use categories are used to organize the different habitat types and species that utilize them in the Bay.

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31.	Section 3.1.1.1, Water, Page 3-2, Last few lines.	The PFD suggests that generally only bay anchovy and an unidentified goby are spawned in Newark Bay (with regard to ichthyoplankton). Is that accurate/an acceptable hypothesis based on all available data? On pg. 3-3, it's noted that all life stages are present for bay anchovy, winter flounder, weakfish, and windowpane flounder. Please qualify the text as appropriate.	The bay anchovy and goby were captured in only one year of data collection (1993-1994), while the other species were captured over several years of data collection (1999-2006). Text will be clarified.
32.	Section 3.1.1.1, Page 3-2, Water, last sentence.	The reference to the term "benthos" appears inappropriate here; replace with "sediment."	Edit will be made as suggested.
33.	Section 3.1.1.1, Benthic Invertebrates, Page 3-3.	Please clarify or define 'feeding' in the sentence "Feeding and anoxic voids were abundant in June."	The sentence will be deleted.
34.	Section 3.1.1.1, Water - Fish, Page 3-6, First complete paragraph, Third from last sentence.	Please correct spelling of Atlantic silverside binomial to *Menidia menidia*.	Edit will be made as suggested.
35.	Section 3.1.1.1, Water - Fish, Page 3-6, Second complete paragraph, Fourth sentence.	Please revise the sentence to indicate that the listed species dominated the fauna obtained from the survey but not the "catch at each station".	The words "at each station" will be deleted.
36.	Section 3.1.1.3, Forested Areas - Birds, Page 3-10.	2nd paragraph: Shooters Island is located within the boundaries of Newark Bay proper and not the Arthur Kill or Kill van Kull. Please correct in the text. 4th paragraph: Please list the waterfowl species known/suspected to breed in Newark Bay.	The second paragraph will be edited as suggested. A list of waterfowl species that may breed in the Bay will be provided.
37.	Section 3.1.1.3, Forested Areas – Mammals, Page 3-11.	Correct misspelling of "possum" in the third line of the first paragraph under "Mammals" to "opossum."	Edit will be made as suggested.

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38.	Section 3.1.1, Forested Areas, Page 3-11.	It is unclear why a discussion of marine mammals is presented in Section 3.1.1.3, Forested Areas. In addition, the information presented is incorrect and should be revised (and re-located to the appropriate section); harbor seal are observed within the NBSA each year and should be expected to be present.	The discussion of marine mammals will be moved to an appropriate section of the revised PFD. Although there is no documentation of harbor seals in the NBSA, harbor seals are depicted in the list of receptors of interest on page 4-17. It should be noted however, that at this stage in the ERA process (i.e., the BERA), Tierra is attempting to reduce uncertainty and conservatism in risk estimates that were provided in the SLERA. Modeling to receptors that are unlikely to exist or inhabit the Bay is adding unnecessary uncertainty and conservatism to the conclusions of the risk assessment.
39.	Section 3.1.1.3, Forested Areas – Mammals, Page 3-12, Last sentence.	The phrase "will avoid tainted areas" is ambiguous (what is a "tainted" area) and seems to imbue these animals with anthropomorphic choices about where they choose to dwell. Please revise the text to state that they have been extirpated from much of their historical range due to a number of factors including habitat loss and contaminant related effects.	Text will be revised as suggested.
40.	Section 3.1.1.4, Urban Landscape, Page 3-12.	Residential use property abutting and near the NBSA shoreline should be additionally described, and depicted in Figure 3-1, as this use is a significant feature of the urban landscape too. Please provide a figure showing shoreline elevations and topography with respect to residential properties adjacent to Newark Bay.	As agreed-to during the 1/22/13 call with EPA, capturing and depicting shoreline elevations and topography will be addressed during sampling. These assessments and findings will be included in later documents and will not need to be addressed in the revised PFD.
41.	Section 3.1.1.4, Urban Landscape, Page 3-12, First paragraph, Last sentence.	Unclear what a "concentrated" volume of stormwater is referring to – please clarify.	The words "concentrated volumes of" will be deleted.
42.	Section 3.1.2.1, Threatened and Endangered Species, Page 3-13, Exhibit 3-1.	Please correct spellings of "*Falco peregrinus*" and "*Ischnura ramburii*".	Edit will be made as suggested.

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43.	Section 3.1.2.2, Humans, Page 3-15, Third Bullet.	The discussion regarding fences needs to be modified since under the Superfund law risks are evaluated in the absence of remedial actions or Institutional Controls, which include fences. See also Appendix B.	The discussion regarding fences will be modified accordingly.
44.	Section 3.1.2.2, Humans, Page 3-15, Exhibit 3-2.	The "non-industrial" classification scheme should be revised to reflect current, actual land zoning categories of residential, recreational, commercial, etc. The term "non-industrial, no access" gives a reviewer no information on the current or potential future use for this land, and is therefore not useful for risk assessment purposes. Please revise the text to provide additional information on land use. In general, it is unclear how the information provided in Exhibit 3-2 will be used in the risk assessment; please provide clarification.	The "non-industrial, no access" land use category will be removed, and the land use categories will be revised to closely match those associated with zoning designations.
45.	Section 3.1.2.2, Humans, Page 3-16, Exhibit 3-3.	These four areas should be shown on a figure (or Figure 3-1), perhaps indicated with hatched lines for potential residential developments.	These four areas will be added to a new figure or to the existing Figure 3-1.
46.	Section 3.2.1, Secondary Data Evaluation, Page 3-17, first paragraph.	In addition to the referenced E. Butler correspondence, USEPA also identified secondary data sources to be evaluated in comments submitted to TSI and dated 23 May 2012.	Additional secondary data sources will be provided as suggested.
47.	Section 3.2.2, Sediment Data.	Please clarify the discussion of existing data to note where congener data is available.	Text will be clarified to note that PCB congener data have been collected throughout the Bay during the Phase I and Phase II Sediment Investigations and are available in the Phase I and Phase II Sediment Investigation Field and Data Report (Tierra 2008).
48.	Section 3.2.2, Sediment Data, Page 3-18, Last paragraph, Last sentence.	The statement is open ended and unclear as to which emerging chemicals would be evaluated and what the rationale for selection would be. At the NBSA BERA Workshop, it was decided that polychlorinated naphthalenes (PCNs) and polybrominated diphenyl ethers (PBDEs) would be considered for inclusion in the risk assessment. EPA is not considering the inclusion of additional emerging contaminants.	The text will clarify that the only emerging constituents currently being considered are PCNs and PBDEs. The EPA emerging contaminants web page will be reviewed periodically to ensure that any other emerging contaminants that are relevant to Newark Bay are identified and included in the risk assessment.

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49.	Section 3.2.2.1, Sediment Chemistry Data, Page 3-19.	This section states that the risk assessments will focus on the BAZ, i.e., "surficial sediments" or the upper 15 cm. Failure to consider deeper layers of contamination will likely underestimate the potential risk to human and ecological receptors in the event that human (e.g., boat traffic, dredging) or storm-related disturbance of the sediment occurs. Due to a potential future exposure scenario that could expose receptors to deeper, contaminated sediments not currently present in the BAZ, it should be noted that preliminary remediation goals (PRGs) developed from the risk assessment will need to be applied to future scenarios where deeper sediments may be exposed by erosion or human disturbances during the NBSA FS and remedial design.	Comment noted.
50.	Section 3.2.3.1, Tissue Chemistry Data, Page 3-21, Exhibit 3-4.	Please verify that the reported average lipid for American eel from the CARP dataset is 17%. This value appears to be high.	The average lipid concentration for the American eel captured from Newark Bay is indeed 17%. Note that this is based on only 2 samples (6.5% and 27.3% lipid).
51.	Section 3.2.3.1, Tissue Chemistry Data, Page 3-21, end of second paragraph.	Include a brief summary of the data analyses performed regarding the three islands, and/or citations for such analyses.	A brief summary of the data analyses performed will be provided along with the citation.
52.	Section 3.2.3.2, Bioaccumulation Studies, Page 3-22.	The Wintermyer & Cooper (2003) oyster uptake study should be discussed here as a relevant source of site- specific information.	The Wintermyer and Cooper (2003) study will be referenced as appropriate.

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53.	Section 3.2.3.2, Bioaccumulation Studies, Page 3-22, Second paragraph, Last sentence.	Please explain why the calculated biota sediment accumulation factors (BSAFs) are so uncertain. If this is the case, the explanation will be useful information for the upcoming study design.	Calculated BSAFs for the inner harbor ranged as follows: PCB congeners, 0.16 to 1.38; PCDD/Fs, 0.05 to 0.27; pesticides, 0.15 to 2.82; PAHs, 0.01 to 0.24. The dataset used to calculate BSAFs from CARP is small and the limited paired sediment-tissue data do not appear to demonstrate a statistical relationship, based on the large range of BSAFs. If Equilibrium Partitioning Theory is to be believed, and organic carbon and lipid account for the variability, then the BSAF values should be the same or at least within the same order of magnitude for each constituent. Because, for each constituent group, the BSAFs are an order of magnitude or more different, they are considered uncertain. A brief description of the uncertainty will be provided in the text.
54.	Section 3.2.3.2, Bioaccumulation Studies, Page 3-22, Last paragraph, Last sentence.	Please revise sentence to clarify what "achieve equilibrium" means; the meaning would not be intuitively obvious to someone with a non-technical background.	Text will be clarified as suggested.
55.	Section 3.2.3.3, Tissue Ingestion Data	As a point of clarification, the discussion of the Creel/Angler Surveys should emphasize that the evaluation will concentrate only on those individuals within the survey who have reported consuming fish/crabs. Consistent with EPA Guidance, the consumption rate should reflect the 90th percentile or higher. The discussion should also reflect EPA's analysis of fish/crab consumption based on the original data. The resulting calculated fish/crab ingestion rates should be presented in the document.	As agreed-to during the 1/22/13 call with EPA, the fish/crab ingestion rates will be discussed in the PAR, along with the additional exposure parameters. They will be presented in RAGS Part D tables. Exposure parameters, including ingestion rates, do not need to be addressed in the revised PFD.

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56.	Section 3.2.3.3, Tissue Ingestion Data, Page 3-24, Exhibit 3-5.	Under the heading Creel/Angler Surveys, the document states there have been four major creel/angler surveys for the area in and around the NBSA, and cites May and Burger (1996), Pflugh et al. (1999), Burger et al. (1999), and Burger (2002). It should be clarified that Pflugh et al. (1999) and Burger et al. (1999) are evaluations of the same 1995 survey of the Newark Bay complex. Please confirm whether the Burger (2002) study included the Passaic River.	The requested clarifications/information regarding Pflugh et al. (1999), Burger et al. (1999) and Burger (2002) will be added. The Passaic River was not identified in Burger (2002); thus it was concluded that Burger (2002) did not include the Passaic River.
57.	Section 3.2.3.3, Tissue Ingestion Data, Last paragraph.	In addition, NJ advises against eating white catfish and striped bass by high-risk individuals, and NYSDOH advises this population to not eat any fish from Newark Bay. There is also an enforceable ban on harvest of blue crab, as well as prohibition on the sale of blue crab, striped bass or American eel. Current federal regulation requires all anglers to register with their state or the federal government to fish in marine waters. The free saltwater registry for NJ can be found on: http://www.nj.gov/dep/fgw/marinelicenses.htm. Please add this information to the document.	The requested information regarding fish and crab advisories, bans, regulations, and the saltwater registry will be added.
58.	Section 3.2.4, Surface Water Data, Page 3-26.	Although it is true that it was decided that exposure to pathogens would not be addressed in the NBSA HHRA during the June 2011 Workshop, pathogens are not included as a contaminant under CERCLA, so the text should be deleted.	The text referring to pathogens will be deleted.
59.	Section 3.2.4.1, Surface Water Chemistry Data, Page 3-26.	There are extensive water chemistry data from 2000 to 2002 collected under NJDEP's New Jersey Toxics Reduction Work Plan (NJ portion of CARP program) for the NBSA. See: http://www.state.nj.us/dep/dsr/njtrwp/I-D-SITProjRep.pdf. The data in electronic format should also be available from the CARP database: http://www.carpweb.org/main.html. These data need to be evaluated for potential inclusion in the risk assessments.	Surface water chemistry data from CARP have been evaluated under the secondary data evaluation process. As noted on Exhibit 4-1, the data were deemed usable as Level 2 and were therefore excluded from quantitative evaluation with Level 3 data. Certain aspects of the program (notably a lack of documented data validation) precluded its designation as a Level 3 dataset and full usability.
60.	Table 3-2	It is not clear what "Species Count" is indicating on the column heading, when the rows are mostly individual species. Is this number of individuals or number of stations detected? Please clarify.	The header is in reference to the total number of individuals found among all stations in the study. A note will be added to the table to clarify.

Comment No.	Section, Page No., Paragraph	Comment	Response
61.	Section 4, General Comment.	Throughout this section, the use of benchmarks from the literature needs better explanation. Will the NOAEL or LOAEL be used? If multiple values are available, how will the benchmark be selected? Please describe specifically how screening benchmarks and toxicity reference values (TRVs) will be applied.	Text that describes the selection of benchmarks and TRVs is more detailed than the scope of this PFD. Details regarding the procedures for TRV selection and benchmarks will be provided in future documents.
62.	Section 4, Baseline Ecological Risk Assessment, Page 4-1.	This section should identify the activities that need to be completed during the baseline problem formulation for the BERA. Although this information is included in Section 1 ("Introduction"), it should be presented in this section again. The activities should include: a. Refine the preliminary list of COPECs at the site (i.e., those that were identified during the SLERA), b. Further characterize the potential ecological effects of the COPECs at the site, c. Review and refine the information on the fate and transport of COPECs, the potential exposure pathways, and the receptors potentially at risk, d. Select assessment and measurement endpoints, and e. Develop of refine a conceptual model (CSM) with testable hypotheses (or risk questions) that the site investigation will address.	The activities that will be completed in the PFD will be restated in Section 4.
63.	Section 4, Baseline Ecological Risk Assessment, Page 4-1.	This section should also indicate that there is a scientific/management decision point at the conclusion of the problem formulation (USEPA 1997a) that consists of agreement on: a. Assessment Endpoints, b. Exposure Pathways, c. Risk Questions, and d. CSM that integrates these components.	A SMDP will be identified in this section.

Comment No.	Section, Page No., Paragraph	Comment	Response
64.	Section 4.1, Refinement of COPECs, Page 4-1.	The description of the updated COPEC screen is unclear. A complete description of the methods that were used to refine the list of COPECs that will be evaluated in the BERA should be provided and should describe: a. The selection criteria used to identify relevant data for identifying COPECs and the rationale used to develop those criteria (e.g., quality of data, age of data, etc.). b. The data sets that were compiled to support the updated COPEC screen (including both a list of the data sets that were evaluated and the list of the data sets that met the criteria). c. The toxicity screening values (TSVs) that were selected to support the identification of COPECs (e.g., tables of the TSVs for water, sediment, and tissues), complete citations for each TSV, and the rationale for selecting the TSVs. Although multiple sources of TSVs were identified in Section 4.1.2, it is unclear how TSVs from the various sources were prioritized for use in screening the COPECs. If the previously approved SLERA methodology was followed, please cite that. d. The methods that were used to conduct the updated COPEC screen including how the exposure point concentrations were established (including the methods used to treat non-detect values), how the COPECs were identified, and how COPECs were addressed when no data or TSVs were available (Note: they should be retained in the BERA).	Please refer to Section 4.1.2. Additional text will be added to this section to clarify the points in the comment as needed.
65.	Table 4-2.	Why is only 2,3,7,8-TCDD listed as a COPEC in the table? All dioxin/furan congeners should also be listed as COPECs.	2,3,7,8-TCDD is the only dioxin/furan congener with an ecological screening benchmark. All other congeners are evaluated based on the toxicity of 2,3,7,8-TCDD under the toxicity equivalency (TEQ) approach. The analytical program will include the major dioxin/furan congeners. The table will be updated to reflect that all congeners are COPECs.

Comment No.	Section, Page No., Paragraph	Comment	Response
66.	Section 4.1.1, Summary of COPECs from SLERA, Page 4-1.	Please describe how COPECs based on bird and mammal diet will be identified.	COPECs based on bird and mammal diet were identified in the SLERA. However, the COPEC list will be refined based on results of the fish and benthic invertebrate tissue analyses. Text will be added to clarify.
67.	Section 4.1.2, Updated COPEC Screen, Page 4-2.	It is inappropriate to eliminate the CARP datasets from the screen; these data should be included.	CARP sediment data went through EPA's approved secondary data process and were designated Level 2. Although it appears the data have been validated, they were given CARP "alert" qualifiers such as "use," "do not use," and "use with caution." Such alerts do not comport with standard Region 2 data validation qualifiers. As a result, the CARP sediment dataset was excluded from the COPEC screen. However, a review of the CARP data indicates that concentrations fall mid-range within Tierra's data. Thus, the final COPECs from the screen would be the same either with or without incorporation of the CARP dataset.
68.	Section 4.1.2, Updated COPEC Screen, Page 4-2, Second Paragraph, Last sentence.	Please modify the sentence that begins "As such, they are deemed rigorous and robust and can be utilized..." to begin "As such, they can be utilized..."	Edit will be made as suggested.
69.	Section 4.1.2, Updated COPEC Screen, Page 4-2.	The text should be revised to avoid the perception that all data require peer-review for inclusion as Level 3. Any data that has been collected under an approved quality assurance plan and has undergone QA/QC review should be considered. Therefore, please change the CARP surface water dataset in Exhibit 4-1 to data level 3 so that it may be used in the risk assessment, as these data were collected under a comprehensive QA/QC plan and underwent QA/QC review.	The suggestion in this comment contradicts the secondary data evaluation process, which was approved by EPA. Only validated data will be quantitatively used in the risk assessment. The CARP surface water database says DRAFT for all CARP surface water data; thus it does not appear these data have been validated.

Comment No.	Section, Page No., Paragraph	Comment	Response
70.	Section 4.1.2, Updated COPEC Screen.	The analytes to be included in the BERA should not be limited to those identified in Table 4-1, Summary of COPECs from the SLERA. The full suite of PCB congeners need to be included in sediment and tissue (at least on a percentage of the samples) for the purposes of verifying Aroclor totals and for identifying sources/gradients.	The analytes for the BERA will rely on those listed in Table 4-1 as a starting point. In order to obtain data for Total PCBs and to verify Aroclor totals, individual PCB congener data will be collected.
71.	Table 4-1	In Table 4-1, it is unclear why different types of mercury are identified as COPECs for different media; please clarify.	Table 4-1 has been excerpted directly from the SLERA (Table 11). Unfortunately, there is no discussion in the SLERA that explains these differences.
72.	Section 4.1.2, Updated COPEC Screen, Page 4-3.	The text indicates that a screen was not conducted to identify COPECs in surface water due to limitations on the available data, but Exhibit 4-1 indicates that data on the concentrations of COPECs in surface water are available for up to 550 analytes in more than 600 surface water samples. Please clarify the limitations on the available surface water chemistry data regarding identification of surface water COPECs in the NBSA.	Please refer to responses to Comments #59 and #69 regarding the CARP surface water dataset. Surface water sampling programs are currently ongoing in the Bay. A surface water COPEC screen will be conducted once all data have been collected and validated.
73.	Section 4.1.3, Revised Sediment COPEC Screen Results, Page 4-3.	Please clarify if all 89 COPECs identified in Table 4-2 will be evaluated for each receptor group.	All identified COPECs will be analyzed for in sediments, benthic invertebrate and fish tissue. Following analysis, the COPEC list for birds and mammals will be refined.

Comment No.	Section, Page No., Paragraph	Comment	Response
74.	Table 4-2	In Table 4-2, Surficial Sediment COPEC Screen: a. It is unclear whether the reported total Toxic Equivalent (TEQ) values include the sum of the TEQs that were calculated for polychlorinated dibenzodioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and coplanar polychlorinated biphenyls (PCBs). The total TEQs should include all three classes, b. The hierarchical process that was used to select the TSVs needs to be described in the table footnotes, c. TSVs have not been compiled for many of the substances included in the table. The table needs to be revised to include uncertain COPECs as COPECs that will be retained in the BERA, d. The table should be revised to include footnotes that describe how the various totals were calculated [e.g., total WHO dioxin TEQ - bird, total DDTs, total PCBs, total polyaromatic hydrocarbons (PAHs), etc.], e. In some cases, few data were available to determine the maximum concentration of a substance in sediment (in some cases as few as three samples). As part of the overall description of the screening methods, a minimum number of samples that need to be evaluated to exclude a substance as a COPEC should be defined, and f. It is unclear how frequency of detection, mean, minimum, standard deviation, geometric mean, or median were used in the updated COPEC screen.	The COPEC screening table will be updated to clarify the points in the comment. Please note, with regard to "b," the hierarchical process is described in the footnotes, but will be clarified. With regard to point "e," a frequency of detection screen will be incorporated as suggested. The mean, minimum, standard deviation, geometric mean, and median were not used in the COPEC screen, but are useful statistical information designed to inform the reader of the overall data distribution.
75.	Section 4.1.4, Constituent Fate and Transport.	This entire section, pages 4-4 to 4-10, covers general characteristics of the contaminant categories being considered in this study. Given the 9 plus years of study conducted so far (Phase I and II sediment investigations, SLERA, information from Tables 4-1 and 4-2 of this PFD), this section should be supplemented with site-specific information on key contaminants per category to allow for initial focus for the forthcoming risk assessments.	For robust discussions regarding the nature and extent and site-specific fate and transport of these COPECs, please refer to the DEAR and upcoming revised CSM.

Comment No.	Section, Page No., Paragraph	Comment	Response
76.	Section 4.1.4, Constituent Fate and Transport and Section 4.1.5, Ecotoxicity, General Comment.	These sections deal with metals, PAH, PCBs, pesticides, dioxins/furans and bis(2-ethylhexyl)phthalate only. There are other compounds in Table 4-2 that have screening values and were identified as COPECs, but the document does not discuss how they will be handled. Many of these compounds are chlorine substituted monoaromatics, such as 1,2,4-trichlorobenzene and 1,4-dichlorobenzene. Structurally these compounds are type I narcotics and the USEPA has provided guidance on how to compute sediment (and water) benchmarks for such chemicals which have a non-specific mode of action (USEPA, 2008). Similarly, equilibrium partitioning methods based on carbon normalization should also be used to assess the potential for effects of other neutral organic COPECs that act by specific modes of action. The discussion needs to be expanded to describe how each type of compound will be handled.	As agreed-to during the 1/22/13 call with EPA, this information will be incorporated into future risk assessment documents as needed (e.g., subsequent work plans or the BERA report).
77.	Section 4.1.4.1, Metals, Page 4-4, 2nd Paragraph, 1st sentence.	Revise to "Some metals are considered essential nutrients in plants and animals and net uptake may be regulated as such over a limited range of concentrations (ATSDR, 2004; Wood, 2012).	Edit will be made as suggested.
78.	Section 4.1.4.1, Metals, Page 4-4, end of 2nd Paragraph.	Insert a statement indicating "This ability is likely to be exceeded at excessively high concentrations."	Edit will be made as suggested.
79.	Section 4.1.4.1, Metals, Page 4-4, New Paragraph.	Insert a paragraph about AVS and SEM- "Consideration of AVS and SEM provides a way to screen out situations where toxicity due to sediment SEMs (Cu, Cd, Ni, Pb and Zn, and also Ag) is not expected (USEPA, 2005, 2007).	Edit will be made as suggested.
80.	Section 4.1.4.2, PAHs, Page 4-4, 1st line in section.	Revise to "PAHs are a large group of organic chemicals....." PAHs are not necessarily chlorinated.	Edit will be made as suggested.
81.	Section 4.1.4.2, PAHs, Page 4-5, 1st paragraph.	The discussion of volatilization/Henry's law constant should be moved to paragraph 2 on physio-chemical properties.	Text will be revised as suggested.

Comment No.	Section, Page No., Paragraph	Comment	Response
82.	Section 4.1.4.2, PAHs, Page 4-5, 1st paragraph, 11th line.	Revise to "temperature, and microorganisms present."	Edit will be made as suggested.
83.	Section 4.1.4.2, PAHs, Page 4-5, 1st paragraph.	Mention the impact of dissolved organic carbon on PAHs as well.	Text will be added as suggested.
84.	Section 4.1.4.2, PAHs, Page 4-6, new Paragraph.	Insert a paragraph at end of PAH section along the lines of the following: "Although individual PAHs may be toxic to an organism by a compound-specific mode of action, it is well known that PAHS also exert toxicity non-specifically, by narcosis. Because it is a non-specific mode of action it is necessary to consider the toxicity of the mixture as a whole, in addition to the toxicity of any individual compounds that are present in the mixture. The target lipid model (TLM; Di Toro et al., 2000; Di Toro and McGrath, 2000; McGrath et al., 2009) provides a way to quantify the narcotic effect of PAH mixtures while considering PAH bioavailability as well (USEPA, 2002; 2008)."	Text will be added as suggested.
85.	Section 4.1.4.5, Dioxins and Furans, Page 4-9.	Please add information about dioxin being generated as a byproduct from production of Agent Orange and as a byproduct of combustion.	Edit will be made as suggested.
86.	Section 4.1.4.6, Bis(2-ethylhexyl)phthalate, Page 4-9, Last paragraph, Second sentence.	Replace "move" with "disperse".	Edit will be made as suggested.
87.	Section 4.1.5, Ecotoxicity of COPECs.	The information on the ecotoxicity of the selected COPECs needs to be expanded to include information on the toxicity of the selected COPECs to each of the ecological receptor groups potentially at risk (i.e., plants, invertebrates, fish, reptiles, amphibians, birds, and mammals).	The available information has been summarized as appropriate. Limited information exists for all receptor groups and all COPECs. As agreed-to during the 1/22/13 call with EPA, additional information, as available, will be incorporated into future risk assessment documents (e.g., sampling plans, BERA report).

Comment No.	Section, Page No., Paragraph	Comment	Response
88.	Section 4.1.5.1, Metals, Page 4-10.	Please cite EPA's Framework for Metals Risk Assessment (EPA 120/R-07/001) in this section.	Edit will be made as suggested.
89.	Section 4.1.5.1, Metals, Page 4-10, end of 1st Paragraph.	Insert: "It is particularly useful for identifying samples in which toxicity due to SEM metals is not likely to occur (USEPA, 2005)."	Edit will be made as suggested.
90.	Section 4.1.5.1, Metals, Page 4-10, 2nd Paragraph, 1st sentence.	As written, it sounds as if metals that are essential nutrients might not cause adverse effects. Indicate that "Some metals can act as essential nutrients to plants (e.g., copper, nickel, zinc and others) at low to moderate concentrations but be toxic at higher concentrations. Others ... "	Edit will be made as suggested.
91.	Section 4.1.5.1, Metals, Page 4-10, 2nd Paragraph, 5th Line.	Revise to "... may include decreased survival, growth, reproduction, ..."	Edit will be made as suggested.
92.	Section 4.1.5.1, Metals, Page 4-10, 2nd Paragraph, 9th Line.	Revise to "changes to survival, growth, reproductive and developmental success and behavior..."	Edit will be made as suggested.
93.	Section 4.1.5.1, Metals, Page 4-10, 2nd Paragraph, 10th line.	Revise to "... develop tolerance to limited concentrations of certain metals ..."	Edit will be made as suggested.
94.	Section 4.1.5.2, PAHs, Page 4-11.	In addition to explaining the photodegradation potential for PAHs, the document should also cite the potential for photo-induced toxicity of PAHs. Please cite some of the well-known work by authors such as Oris, J.T., Barron, M.G., Ireland, D.S., and others. EPA can provide citations upon request.	Citations will be added as suggested.
95.	Section 4.1.5.2, PAHs, Page 4-11, 2nd Paragraph, before last sentence.	Insert "Because narcosis is a non-specific mode of action and the effects are additive, it requires that the toxicity of PAH mixtures be considered (Swartz et al., 1997; Di Toro and McGrath, 2000; USEPA, 2008)."	Edit will be made as suggested.

Comment No.	Section, Page No., Paragraph	Comment	Response
96.	Section 4.1.5.3, PCBs, Page 4-12, Second full paragraph, Last sentence	Add information on effects in mammals, since the preceding sentence indicates they are more sensitive than avian species.	Additional text regarding effects in mammals will be added as suggested.
97.	Section 4.1.5.4, Organochlorine Pesticides, Page 4-13, end of 2nd Paragraph.	Insert "The bioavailability and effects on benthic organisms of DDT (and other nonionic organic chemicals acting by a specific mode of action) may be evaluated by use of equilibrium partitioning methods (USEPA, 2000, 2008).	Edit will be made as suggested.
98.	Section 4.2, Ecological Conceptual Site Model.	Figure 4-2, Ecological Exposure Pathways, should be revised as follows: a. The aquatic invertebrates should reflect the three groups selected for evaluation in the BERA, b. The mammals should include the three groups selected for evaluation in the BERA (i.e., omnivorous mammals are missing), c. Ingestion of tissue needs to be identified as a major and complete exposure pathway for benthic fish and some epifaunal invertebrate species, and, d. Ingestion and direct contact with intertidal sediments need to be identified as major and complete exposure pathways for benthic fish (many of these species likely forage in intertidal areas during high tide).	Figure 4-2 will be updated to reflect the receptor categories described in the text, as suggested in points "a" and "b." However, Tierra disagrees with points "c" and "d" being major and complete exposure pathways because these pathways are not anticipated to be quantitatively evaluated in the BERA. The legend will be updated to reflect major pathways that are anticipated to be quantitatively evaluated (denoted with an "X") vs. minor pathways that will be qualitatively evaluated (denoted with an "O").
99.	Section 4.3, Ecological Exposure Pathways and Receptors, Page 4-15, First bullet, First sentence.	Please clarify if there are additional relevant exposure pathways to those listed. The wording "...have the greatest potential" suggest that additional pathways exist but the aforementioned list appears comprehensive.	The text is meant to state that ecological species in close contact with sediment (either through direct contact or ingestion) have greater potential for exposure to sediment-associated COPECs than other ecological species. Text will be modified to make this point clearer.

Comment No.	Section, Page No., Paragraph	Comment	Response
100.	Section 4.3, Ecological Exposure Pathways and Receptors, Page 4-15, First bullet, Last sentence.	Providing an example of a species that fit the identified criteria would be helpful.	Example species will be provided as suggested.
101.	Section 4.3, Ecological Exposure Pathways and Receptors, Page 4-15, Paragraph at bottom of page.	The reference to ecological receptor exposure via the inhalation pathway needs to be removed as this pathway cannot be modeled or considered reliably for ecological risk decision making.	The inhalation pathway will be removed as suggested.
102.	Section 4.3, Page 4-16, First paragraph.	Please add the following sentence: "Species with known locational (e.g., site) fidelity for all or part of their life history were considered in the selection of receptors."	Edit will be made as suggested.
103.	Section 4.3, Ecological Exposure Pathways and Receptors, Page 4-15.	Please change "Ecological species" to "Ecological receptors" in the first bullet item (first line).	Edit will be made as suggested.
104.	Section 4.3, Ecological Exposure Pathways and Receptors, Page 4-15, last paragraph.	This section provides a description of ecological exposure pathways that is limited to one sentence. This section should provide a robust description of the pathways through which ecological receptors can be exposed to COPECs, including a general description of the behavior of the COPECs at the site and the relevant exposure pathways for the various receptor groups for each of the following: a. Bioaccumulative substances, b. Substances that partition into sediments/soils, c. Substances that partition into surface water, and d. Substances that partition into the surface microlayer.	As agreed-to during the 1/22/13 call with EPA, this level of information and detail will be incorporated into future RI/FS and risk assessment documents (e.g., updated CSM, BERA).

Comment No.	Section, Page No., Paragraph	Comment	Response
105.	Section 4.3, Ecological Exposure Pathways and Receptors, Page 4-16 and 4-17.	The bulleted list of representative receptors presented in the text/trophic categories do not match up with the receptor list presented in the CSM (Figure 4-2) (e.g., benthic infauna vs. benthic invertebrate community, pelagic invertebrates vs. plankton, pelagic fish vs. pelagic predatory fish, carnivorous birds vs. piscivorous birds). Please reconcile the terminology. Also, omnivorous mammals are included in the list of bullets on page 4-17, but not in Figure 4-2.	The terminology between the text and Figure 4-2 will be reconciled as suggested.
106.	Section 4.3, Ecological Exposure Pathways and Receptors, Page 4-16, and Figure 4-2.	Why are "Channel sediments" not listed here?	Please refer to Comment #24, which states "These areas … have been deepened such that no historical sediment deposits presently reside in these areas and these areas (both Port and Navigation Channels) require regular maintenance dredging…" Due to regular maintenance dredging, no exposure pathways exist to ecological receptors from channel sediments and they will not be quantitatively evaluated in the BERA.
107.	Section 4.3, Ecological Exposure Pathways and Receptors, Page 4-16, first paragraph.	Habitat, rather than geomorphic and geographic areas, is a much better way to describe the exposure areas for ecological receptors, and should be referenced here.	Text will be revised to incorporate habitat-based exposure areas as well as both geomorphic and geographic areas.
108.	Section 4.3, Ecological Exposure Pathways and Receptors, Page 4-16.	Aquatic plants, one of the ecological receptor groups potentially at risk, should be divided into phytoplankton and aquatic macrophytes because the exposure pathways for these two receptor groups are different (i.e., surface water vs. surface water and sediment).	The aquatic plant receptor group was established at the BHHERA Workshop. There is no reason to subdivide this receptor group.
109.	Section 4.3, Ecological Exposure Pathways and Receptors, Page 4-16.	The examples used to illustrate the three groups of aquatic invertebrates identified were not always correct. For example, Macoma was included with the epifaunic invertebrates when it would be more appropriate to include these mollusks in the benthic infaunal group of invertebrates.	The suggested revisions are inconsistent with the categories discussed and decided upon by Tierra and the agencies at the BHHERA Workshop (refer to Workshop Meeting Minutes, dated December 1, 2011, specifically Table 1).

Comment No.	Section, Page No., Paragraph	Comment	Response
110.	Section 4.3, Ecological Exposure Pathways and Receptors, Pages 4-16 to 4-17.	The rationale for selecting the three groups of fish, five groups of birds, and three groups of mammals as receptors potentially at risk in the NBSA should be briefly provided (e.g., differences in exposure pathways).	The rationale for the selection of different trophic groups will be provided as suggested.
111.	Section 4.3, Ecological Exposure Pathways and Receptors, Pages 4-16 to 4-17.	Prior documents indicated that risk to reptiles will be evaluated qualitatively. Therefore, a discussion regarding the evaluation of reptiles should be added to the document.	A qualitative discussion about reptiles will be added as suggested.
112.	Section 4.3, Ecological Exposure Pathways and Receptors.	A complete list of all threatened and endangered species and other species that have been reported to utilize habitats in the study area need to be included in this section (some of this information is in Section 3). The New York Bight distinct population segment (DPS) of the Atlantic sturgeon is federally listed as endangered. As noted in Section 3, Atlantic sturgeon has been identified as present in Newark Bay. Based on input from the National Marine Fisheries Service (Damon-Randall, pers. comm., 2013), since Newark Bay is within the geographic range of the New York Bight DPS, it is likely that Atlantic sturgeon in the NBSA would be from the New York Bight DPS. Fish from other DPSs could also be present in the NBSA. Atlantic sturgeon needs to be included on the list of threatened and endangered species for the BERA.	A comprehensive search/data request from both the NJ Department of Natural Heritage and the NYSDEC was conducted (refer to Appendix A) and the Atlantic sturgeon did not appear on either list; the shortnose sturgeon is included. In over 16 years of catch data, only one Atlantic sturgeon was captured in the Bay (in 1993, refer to Table 3-4).
113.	Section 4.3, Ecological Exposure Pathways and Receptors.	In addition to the examples of species that are included in the various ecological receptor groups, the focal species that will be used in the BERA should be identified.	The list provided in Section 4.3 is meant to be as comprehensive as possible so that all potential receptor species are presented. Additional documents that focus the sampling and analysis for the risk assessments will provide the individual focal species for the BERA.

Comment No.	Section, Page No., Paragraph	Comment	Response
114.	Section 4.3, Ecological Exposure Pathways and Receptors – Birds, Page 4-16.	Please add discussion on the likelihood of a complete exposure pathway for insectivorous birds (and mammals) from sediment-borne contaminants here. Based on the taxa recorded in various macroinvertebrate community surveys, there is little if any insect prey biomass emerging into the air space over Newark Bay. Inclusion of this trophic category was discussed during the June 2011 BHHERA Workshop; however, if the pathway is likely to only represent a de minimus exposure, it would be better to focus on other representative species.	Tierra agrees that evaluation of insectivorous mammals and birds, while potentially present in the NBSA, provide a *de minimus* exposure pathway. However, this receptor group will be evaluated with a food web exposure model, similar to other bird and mammal receptors.
115.	Section 4.3, Ecological Exposure Pathways and Receptors – Mammals, Page 4-17.	The Mink should be added as a receptor of interest in this section.	The mink can be added to the list of receptors of interest; however, at this point in the ERA process (i.e., the BERA), Tierra is attempting to reduce conservatism and uncertainty in the risk estimates. Modeling a receptor that is unlikely to inhabit an urban, estuarine area is adding unnecessary conservatism and uncertainty to the risk assessment.
116.	Section 4.4, Assessment Endpoints, Risk Hypotheses, and Measurement Endpoints.	The following assessment endpoint (AE) should be added: Survival, growth, and reproduction of reptiles.	Edit will be made as suggested.
117.	Section 4.4, Assessment Endpoints, Risk Hypotheses, and Measurement Endpoints, Table 4-3.	All of the testable hypotheses (Sections 4.4.1 to 4.4.5 and in Table 4-3) are expressed as risk questions; the column heading in Table 4-3, Assessment Endpoints, Measurement Endpoints, and Data to be Collected for the NBSA BERA, should be changed to read "Risk Question."	Edit will be made as suggested.

Comment No.	Section, Page No., Paragraph	Comment	Response
118.	Section 4.4, Assessment Endpoints, Risk Hypotheses, and Measurement Endpoints.	The measurement endpoints (MEs) presented (Sections 4.4.1 to 4.4.5 and in Table 4-3) include information on risk analysis methods; the MEs should be revised (e.g., the ME for phytoplankton should be "Concentrations of COPECs in surface water and associated physical and chemical measurements").	This is a measure of exposure. Both measures of exposure (i.e., COPEC concentrations in site media) and measures of effects (i.e., comparisons of COPECs in site media to benchmarks) will be provided.
119.	Section 4.4, Assessment Endpoints, Risk Hypotheses, and Measurement Endpoints, Table 4-3.	Many of the columns included in Table 4-3 provide information that is not relevant to the selection of MEs. Table 4-3 should be revised to include the following columns only: a. Receptor Group, b. Assessment Endpoint, c. Risk Question, and d. Measurement Endpoint.	Edit will be made as suggested.
120.	Section 4.4, Assessment Endpoints, Risk Hypotheses, and Measurement Endpoints, Page 4-17.	Please mention the June 2011 Workshop here as the basis for the selected AEs.	The BHHERA Workshop will be mentioned as the basis of the AEs.

Comment No.	Section, Page No., Paragraph	Comment	Response
121.	Section 4.4, Assessment Endpoints, Risk Hypotheses, and Measurement Endpoints, Page 4-17.	NJDEP recommends that an AE for the protection and maintenance (survival, growth, and reproduction) of bivalve mollusks be included with the PFD. The ME should include bioaccumulation / tissue residue evaluation for the Eastern oyster via a caged bivalve study. This ME could also be considered for the benthic macroinvertebrate AE. All requests to use commercial bivalve species for remedial investigation and risk assessment purposes should be submitted jointly to the persons listed below for a case-by-case decision. Documentation, e.g., draft workplans, should be included with the request. A routine Scientific Collection Permit is also required. Bruce.Friedman@dep.state.nj.us 609-748-2001, Bureau of Marine Water Monitoring Mark.Chicketano@dep.state.nj.us 609-292-9430 Marine Water Enforcement	The AEs were agreed upon at the BHHERA Workshop in June 2011 and recorded in the meeting minutes. Evaluation of bivalve mollusks is included in the AE for the survival, growth, and protection of invertebrates. Please refer to Section 4.4.2, pages 4-19 and 4-20.
122.	Section 4.4.1, Plants, Page 4-18, Assessment Endpoint 1 and Table 4-3.	This AE needs to be re-written as "Survival or growth of aquatic plants and maintenance of plants as a food resource and habitat for fish and wildlife." This edit also needs to be made on Table 4-3.	The AE will be revised as suggested.
123.	Section 4.4.1, Plants, Testable Hypothesis, Risk Question, Page 4-18 and Table 4-3.	This risk question should be rephrased to: "Are the levels of contaminants in surface water and/or whole sediments from the NBSA greater than benchmarks for the survival or growth of aquatic plants?" Please note the use of "or" here instead of "and." This edit also needs to be made on Table 4-3.	Will revise as suggested, but will not use the word "contaminants." At this point in the process they are COPECs.
124.	Section 4.4.1, Plants, Testable Hypothesis, Risk Question, Page 4-18.	What does "relevant exposure areas" mean? It needs to be clarified whenever it is used throughout the document.	Relevant exposure areas are the exposure areas that will be used to assess potential risk to each ecological receptor. Because they are receptor- and habitat-specific, they will be identified and defined following data collection and during the BERA.

Comment No.	Section, Page No., Paragraph	Comment	Response
125.	Section4.4.1, Plants, Testable Hypothesis Risk Question, Page 4-18.	Please remove the use of the parenthetical "(i.e., aquatic thresholds)" throughout the document.	The phrase will be deleted as suggested.
126.	Section 4.4.1, Plants, Page 4-18.	The candidate MEs for aquatic plants should be revised to include the following: a. Concentrations of COPECs in surface water and associated physical and chemical measurements, and b. Concentrations of COPECs in intertidal sediments and associated physical and chemical measurements.	The candidate MEs for aquatic plants will include these measures of exposure. However, they must also include measures of effects which, as discussed in the document, include a comparison of site-collected media with appropriate screening benchmarks.
127.	Section 4.4.2, Invertebrates, Testable Hypothesis/First Risk Question, Page 4-19.	We do not use the term urban regional background. The proper context is regional background concentrations that are collected from areas with similar habitat, physical characteristics, and surrounding land use. Please revise the text accordingly.	The term “urban” will be deleted.
128.	Section 4.4.2, Invertebrates, Testable Hypothesis/First Risk Question, Page 4-19.	Use of a regional (contaminated) urban background is inappropriate for comparison to NBSA benthic communities. Rather a reference population shall be used for comparison.	Text will be revised to indicate a reference population will be used for comparison.
129.	Section 4.4.2, Invertebrates, Testable Hypothesis/Second Risk Question, Page 4-19 and Table 4.3.	This should be re-phrased to: "Are the levels of contaminants in invertebrate tissues from the NBSA greater than tissue benchmarks (e.g., critical body residues) for the survival, growth, or reproduction of invertebrates?" This edit should also be made to Table 4-3.	Will revise as suggested, but will not use the word “contaminants.” At this point in the process they are COPECs.

Comment No.	Section, Page No., Paragraph	Comment	Response
130.	Section 4.4.2, Invertebrates, Testable Hypothesis/Second Risk Question, Page 4-19.	It is not clear how the assessment of potential effects to the invertebrate community will be used to "develop a food web model for upper trophic-level organisms." Please clarify how the assessment will be conducted.	The second sentence in the last paragraph on page 4-19 will be revised. Specifically, text discussing inputs to the food web dose model will be eliminated from this discussion of MEs for invertebrates.
131.	Section 4.4.2, Invertebrates, Testable Hypothesis/Second Risk Question, Page 4-19.	Additional information will need to be included to support the 28-day bioaccumulation test. The additional information should show that steady state is reached in the test organisms, for specific compounds, within the duration of the test.	Such additional information is inappropriate for the scope of the PFD but will be incorporated into future sampling work plans.
132.	Section 4.4.2, Invertebrates, Testable Hypothesis/First Risk Question, Page 4-20 and Table 4-3.	This AE should be re-phrased to: "Are the levels of contaminants in sediments from the BAZ greater than benchmarks for the survival, growth, or reproduction of invertebrates?" This edit should also be made to Table 4-3.	Will revise as suggested, but will not use the word "contaminants." At this point in the process they are COPECs.
133.	Section 4.4.2, Invertebrates, Testable Hypothesis/First Risk Question, Page 4-20, First paragraph.	The re-phrasing of the risk question above would allow it to be answered with one ME, namely the comparison of chemical concentrations in sediment to benchmarks.	Text will be revised as suggested.
134.	Section 4.4.2, Invertebrates, Testable Hypothesis/First Risk Question, Page 4-20, Second paragraph and Table 4-3.	It is recommended that for the laboratory toxicity testing ME there should be a more specific risk question. The following is recommended: "Is the survival, growth or reproduction of invertebrates exposed to whole sediments from the BAZ of the NBSA significantly lower than that in reference sediments?" Note that the use of term "whole sediment" is intended to include both the sediment particles and pore water. This edit should also be made to Table 4-3.	Text and table will be revised as suggested.

Comment No.	Section, Page No., Paragraph	Comment	Response
135.	Section 4.4.2, Invertebrates, Testable Hypothesis/First Risk Question, Page 4-20, Second paragraph.	Verify the species used in Lower Passaic River RI/FS. Additionally the oyster deployment should be for 9 months to measure reproductive effects (see Wintermyer 2003).	The ecological receptors were selected at the BHHERA Workshop with consideration of those used for the Passaic River. Comment regarding oyster deployment is noted.
136.	Section 4.4.2, Invertebrates, Testable Hypothesis/First Risk Question, Page 4-20, 3rd paragraph, Second sentence.	Use of control sediment is for QA/QC purposes; not for making site-related decisions. Ecological risk decisions should be based on responses relative to reference and concentration-response relationships. While this is alluded to below, it is not clearly stated. Please clarify the text.	The text will be clarified to state that control sediment is used for QA/QC purposes, while risk-based management decisions are based on comparison to reference.
137.	Section 4.4.2, Invertebrates, Testable Hypothesis/First Risk Question, Page 4-20, end of 3rd Paragraph.	Insert "Caged bivalve study results will be compared to results obtained at relatively unimpacted reference stations, if practicable."	Edit will be made as suggested.
138.	Section 4.4.2, Invertebrates, Testable Hypothesis/Second Risk Question, Page 4-20 and Table 4-3.	This AE should be re-phrased to: "Are the levels of contaminants in pore water and surface water from the NBSA greater than benchmarks for the survival, growth, or reproduction of invertebrates?" This edit should also be made to Table 4-3.	Will revise as suggested, but will not use the word "contaminants." At this point in the process they are COPECs.
139.	Section 4.4.2, Invertebrates, Testable Hypothesis/Second Risk Question, bottom of Page 4-20.	Last sentence should state "The data use objective for this ME is to estimate the exposure of the benthic invertebrate community to dissolved COPECs in surface water and in sediment pore water."	Text will be revised as suggested.

Comment No.	Section, Page No., Paragraph	Comment	Response
140.	Section 4.4.2, Invertebrates.	The candidate MEs for aquatic invertebrates should be revised to include the following: a. Concentrations of COPECs in surface water from the NBSA and associated physical and chemical measurements, b. Concentrations of COPECs in sediments from the NBSA and associated physical and chemical measurements, c. Concentrations of COPECs in pore water from NBSA sediments and associated physical and chemical measurements, d. Concentrations of COPECs in the tissues of aquatic invertebrates from the NBSA and associated physical and chemical measurements, e. Survival and growth of the amphipod, *Ampelisca abdita*, exposed to sediments from the NBSA and sediments from selected reference areas in 10-d laboratory toxicity tests, f. Survival, growth, and reproduction of the amphipod, *Leptocheirus plumulosus,* exposed to sediments from the NBSA and sediments from selected reference areas in 28-d laboratory toxicity tests, g. Reproduction of eastern oysters, *Crassostrea virginica*, exposed in situ to NBSA sediments and control sediments (i.e., in caged exposures), and h. The ME on community structure will be nearly impossible to assess in an area with so much disturbance. We therefore recommend eliminating this ME. However, if EPA requires inclusion of this ME, it should be revised to read, "abundance, species richness, and other related indicators of benthic invertebrate community structure and associated habitat data in the NBSA and selected reference areas."	The wording and terminology of a, b, c, and d are related to measures of exposure. The remaining MEs (e, f, g, and h) relate to measures of effects. The MEs will be separated as such.
141.	Section 4.4.3, Fish, Page 4-21, First Testable Hypothesis and Table 4-3.	Should be re-written as: "Are the levels of contaminants in fish tissues from the NBSA greater than critical tissue values for the survival, growth, or reproduction of fish?" This edit should also be made to Table 4-3.	Will revise as suggested, but will not use the word "contaminants." At this point in the process they are COPECs.

Comment No.	Section, Page No., Paragraph	Comment	Response
142.	Section 4.4.3, Fish, Page 4-21 First Testable Hypothesis, First Paragraph, Fourth sentence.	Please include as "additional physical and biological information" to be collected (but please note, this list is not exhaustive): COPC concentrations in the tissues (whole body and liver) of fish from the site and reference areas, and associated variables (e.g., percent lipids, fish species, fish length, weight, age, sex). Include targeting of species with relatively small home ranges. Tissue samples for ERA should be at sizes relevant to predator preferences. Tissue samples should be whole body as composites. We normally see 10-20 fish ranging 5 to 20 cm in length. This input should be useful for future discussions on the upcoming QAPP.	Text will be revised as suggested.
143.	Section 4.4.3, Fish, Page 4-21 First Testable Hypothesis, First Paragraph, last sentence.	Change "... compared to tissue-residues for liver." to "... compared to CBRs for liver."	Text will be revised as suggested.
144.	Section 4.4.3, Fish, Page 4-21 Second Testable Hypothesis, and Table 4-3.	Should be rewritten as: "Are the levels of contaminants in pore water, surface water, and sediment from the NBSA greater than benchmarks for the survival, growth, or reproduction of fish?" This edit should also be made to Table 4-3.	Will revise as suggested, but will not use the word "contaminants." At this point in the process they are COPECs.
145.	Section 4.4.3, Fish.	Use of physical parameters in the surface water assessment needs explanation. Will these data be used to 'adjust' the detected levels of contaminants?	Physical parameters such as hardness are used to adjust surface water quality criteria for some metals. Other parameters such as pH, ammonia, and nitrogen provide insight into the quality of surface water in the Bay.
146.	Section 4.4.3, Fish.	For reproductive studies on NBSA fish, the use of cage studies with reference fish should be considered (i.e., fish from an uncontaminated location exposed in-situ in the NBSA).	An *in-situ* caged fish reproductive study will be added as a candidate ME to the second paragraph on page 4-22.
147.	Section 4.4.3, Fish, Page 4-22, First paragraph, and Table 4-3.	Given the limited data on sediment toxicity for fish, what sediment benchmarks will be used to evaluate potential risks of fish exposed to sediment?	Sediment benchmarks are presented on Table 4-2.

Comment No.	Section, Page No., Paragraph	Comment	Response
148.	Section 4.4.3, Fish.	The candidate MEs for fish should be revised to include the following: a. Concentrations of COPECs in surface water from the NBSA and associated physical and chemical measurements, b. Concentrations of COPECs in sediments from the NBSA and associated physical and chemical measurements, c. Concentrations of COPECs in pore water from NBSA sediments and associated physical and chemical measurements, d. Concentrations of COPECs in the tissues of fish from the NBSA and associated physical and chemical measurements, and e. Reproductive health of fish from the NBSA and selected reference areas.	The wording and terminology in a, b, c, and d are related to measures of exposure. The MEs will be separated into measures of effect (e.g., comparison of COPEC in fish tissue to critical body residues) and measures of exposure (e.g., COPEC concentrations in site-collected media).
149.	Section 4.4.4, Birds, Page 4-22, Testable Hypothesis and Table 4-3.	This AE should be re-written as: "Does the daily dose of contaminants received by birds (including piscivorous, benthivorous/sediment probing, omnivorous, insectivorous, and carnivorous birds) from consumption of the tissues of prey species and from other media at the NBSA exceed the toxicity reference values (TRVs) for survival, growth or reproduction of birds? If yes, what are the probabilities of effects of differing magnitude for survival, growth and/or reproduction of birds?" This edit should also be made to Table 4-3.	Will revise as suggested, but will not use the word "contaminants." At this point in the process they are COPECs.
150.	Section 4.4.4, Birds, Page 4-22, Testable Hypothesis, First paragraph.	Surface water concentrations for these food chain models should be whole water concentration (i.e., not filtered, not dissolved conc.). Please amend the text accordingly.	Text will be clarified to indicate that whole water concentrations will be used in the food web models.
151.	Section 4.4.4, Birds, Page 4-22, Testable Hypothesis, First paragraph, Second sentence and Table 4-3.	Please note that estimates of the probabilities of effects of differing magnitude should be obtained and presented. This edit should also be made to Table 4-3.	As agreed-to with EPA during the meeting on 2/22/13, a probabilistic risk assessment will be conducted following the deterministic evaluation.
152.	Section 4.4.4, Birds, Page 4-23, First paragraph and Table 4-3.	EPA prefers to understand the receptor food-chain models that are under consideration. Please identify the specific receptor models that are being proposed for each of these five feeding guilds. This edit should also be made to Table 4-3.	As agreed-to during the 1/22/13 call with EPA, the receptor-specific exposure models will be identified in future risk assessment documents (e.g., sampling plans, BERA report).

Comment No.	Section, Page No., Paragraph	Comment	Response
153.	Section 4.4.4, Birds, Page 4-23, First paragraph.	Surface water concentrations for these food chain models should be whole water concentration (i.e., not filtered, not dissolved conc.). Please amend the text accordingly.	Text will be clarified to indicate that whole water concentrations will be used in the food web models.
154.	Section 4.4.4, Birds, Page 4-23.	The discussion of bird egg tissues is included here and not in Table 4-3. Please revise Table 4-3.	Table 4-3 will be updated to include bird egg tissues.
155.	Section 4.4.4, Birds.	The candidate MEs for birds should be revised to include the following: a. Concentrations of COPECs in the tissues of prey species (i.e., whole body tissue residues) from the NBSA and selected reference areas and associated physical and chemical measurements (e.g., prey size), and b. Concentrations of COPECs in the tissues of birds (i.e., egg, feathers, and/or blood) from the NBSA and selected reference areas and associated physical and chemical measurements.	This ME is related to measures of exposure. The MEs will be separated into measures of effect (e.g., daily doses of COPECs compared to literature-based TRVs) and measures of exposure (e.g., COPEC concentrations in tissues of prey species).
156.	Section 4.4.5, Mammals, Page 4-23, Testable Hypothesis and Table 4-3.	This AE should be re-written to: "Does the daily dose of contaminants received by mammals (including omnivorous, piscivorous, and insectivorous mammals) from consumption of the tissues of prey species and from other media at the NBSA exceed the toxicity reference values (TRVs) for survival, growth or reproduction of mammals? If yes, what are the probabilities of effects of differing magnitude for survival, growth and/or reproduction of mammals?" This edit should also be made to Table 4-3.	Will revise as suggested, but will replace "contaminants" with COPECs.
157.	Section 4.4.5, Mammals, Page 4-23, Testable Hypothesis, First Paragraph, Second sentence and Table 4-3.	Please note that estimates of the probabilities of effects of differing magnitude will be obtained and presented. This edit should also be made to Table 4-3.	As agreed-to with EPA during the meeting on 2/22/13, a probabilistic risk assessment will be conducted following the deterministic evaluation.
158.	Section 4.4.5, Mammals.	Surface water concentrations for these food chain models should be whole water concentration (i.e., not filtered, not dissolved conc.). Please amend the text accordingly.	Text will be clarified to indicate that whole water concentrations will be used in the food web models.

Comment No.	Section, Page No., Paragraph	Comment	Response
159.	Section 4.4.5, Mammals.	The MEs for mammals should be revised to include: Concentrations of COPECs in the tissues of prey species (i.e., whole body tissue residues) from the NBSA and selected reference areas and associated physical and chemical measurements (e.g., prey size).	This ME is related to measures of exposure. The MEs will be separated into measures of effect (e.g., daily doses of COPECs compared to literature-based TRVs) and measures of exposure (e.g., COPEC concentrations in tissues of prey species).
160.	Section 4.5, Ecological Risk Assessment Data Needs, Page 4-23, Table 4-3.	Please revise Table 4-3 so that it is consistent with comments on the AEs, with regard to the table's presentation of AEs, MEs, and data use objectives.	Table 4-3 will be revised as suggested.
161.	Table 4-3	The Table states that "whole body benthic, infaunal invertebrate tissue from 28-day laboratory and/or field bioaccumulation tests using NBSA surface sediment" will be conducted. Specimens with a lifetime exposure should also be collected from the field for comparison.	Whole body tissue residues from field-collected invertebrates (softshell clam and blue crabs) are anticipated to be collected.
162.	Table 4-3	The Table further states that "surface water collected from two depth intervals" will be collected and analyzed. Please clarify the rationale for the two depth intervals to be sampled and be specific regarding the depths.	The table states "surface water collected from two depth intervals (one sample near the sediment-water interface and one sample from 2 feet below the water's surface)." The rationale for this will be provided in the text, not the table.
163.	Table 4-3, Column: Description of Measurement Endpoints.	Please clarify in the text and on the table that this column represents candidate MEs and that further dialogue with EPA will establish the final MEs.	The text and table will be clarified to point out that the MEs are candidate ones and additional dialogue with EPA will establish the final MEs.
164.	Table 4-3, Column: Biological Data/Media to be Sampled.	Please clarify in the text and on the table that this column describes candidate sampling efforts and that further dialogue with EPA will establish the final sampling efforts.	The text and table will clarify that the sampling efforts are candidate ones and additional dialogue with EPA will establish the final sampling efforts.
165.	Table 4-3, Column: Background Evaluation, Row: Urban background datasets.	It will be necessary to collect samples from background reference locations as part of the toxicity testing program. Please note this data need in the document.	The data need that is currently presented in Table 4-3 will also be noted in the text.

Comment No.	Section, Page No., Paragraph	Comment	Response
166.	Table 4-3, Column: Number/Seasonality of Proposed Samples.	Explain why this column is necessary or delete it.	Column will be deleted as suggested.
167.	Section 4.5, Ecological Risk Assessment Data Needs, Page 4-24.	This section does not provide a comprehensive basis for documenting data requirements. The Quality Assurance Project Plan (QAPP) and Work Plan will need to document the data quality objectives (DQOs) for the work needed to fulfill data needs to address the final AEs and MEs. This section needs to be revised to identify all of the data types that need to be collected and/or compiled to support the BERA, including, but not limited to: a. Surface water chemistry data, b. Whole-sediment chemistry data, c. Pore-water chemistry data, d. Whole-sediment toxicity data (i.e., from laboratory and in situ studies), e. Invertebrate-tissue chemistry data, f. Benthic invertebrate community structure data, g. Fish-tissue chemistry data, and h. Bird-tissue chemistry data.	The data needs section provides an outline of upcoming sampling needs, which will be the next step in the BERA process. The data needs outlined by the commenter are analytical ones, which would be further defined and described in upcoming work plans/QAPPs; however, they will be added to this section of the Problem Formulation as suggested.
168.	Section 4.5, Ecological Risk Assessment Data Needs, Page 4-24.	The Problem Formulation document also states that "forage fish, benthic fish, and pelagic predatory fish" will be collected and analyzed. The gut contents should be considered for these fish to determine differences from fish in non-contaminated areas. In addition, analysis of target organs should be considered.	Gut content analyses will be added as candidate measures of exposure for consideration.
169.	Section 4.5, Ecological Risk Assessment Data Needs, Page 4-24.	The Problem Formulation document further states that "whole body invertebrates" will be collected and analyzed. The gut contents should be considered for the blue crabs to determine differences from blue crabs in non-contaminated areas.	As part of blue crab tissue analysis, hepatopancreas from a subset of samples will be analyzed.
170.	Section 4.5, Ecological Risk Assessment Data Needs, Page 4-24, First bullet.	Will all proposed surface sediments include co-located pore water data or only a subset of sediments?	Detailed information regarding the number of samples of porewater and sediment will be provided in future sampling plans.

Comment No.	Section, Page No., Paragraph	Comment	Response
171.	Section 4.5, Ecological Risk Assessment Data Needs, Page 4-24, Second Bullet.	Please be more specific regarding surface water depths to be sampled.	The text will be made consistent with the sampling depths noted in Table 4-3.
172.	Section 4.5, Ecological Risk Assessment Data Needs, Page 4-24.	Please include fish community and avian surveys.	Based on the available data from various bird and fish community surveys, Tierra does not feel that additional fish and bird surveys are necessary. As discussed at the BHHERA Workshop and documented in the Meeting Minutes on page 5, there appears to be enough information to characterize fish and birds, and model selected species.
173.	Section 4.5, Ecological Risk Assessment Data Needs, Page 4-24.	Summary Tables 4-1 and 4-2 indicate that selenium is a COPEC. Please clarify how selenium risks to fish and birds will be characterized and update the document text accordingly.	Focusing on one particular metal to provide detailed information is inappropriate for the scope and level of detail provided in this document. The list of COPECs is large and describing details about each one cannot be done here.
174.	Figure 4-2	The current figure underestimates and ignores complete exposure pathways. For example there is no food pathway for several receptors. The following should be changed to major complete exposure pathways for the tissue ingestion route: crustaceans, forage fish, benthic fish and pelagic fish. All of these consume prey species (e.g., eggs, carcass, fish). In addition, benthic invertebrates and mollusks should be included as major complete pathways. For accuracy the 'tissue' box should be labeled 'food', and would include phytoplankton, zooplankton, detritus, and other tissues. In addition, the ingestion route for intertidal and subtidal sediment should be labeled major for all fish species. Pelagic and benthic fish will seek prey in intertidal waters (e.g., at high tide). Pelagic fish are also known to feed on mollusks. Finally, legacy sediments should be identified as an additional source of contamination.	Please refer to the response to Comment #98.

Comment No.	Section, Page No., Paragraph	Comment	Response
175.	Section 5, Baseline HHRA, Page 5-1, First paragraph.	The third sentence of this paragraph should also be provided in Section 1, Introduction, to explain the PFD concept for the HHRA.	The requested sentence will be added to Section 1.
176.	Section 5.1, HH CSM, Page 5-1.	The text describing the human health CSM refers the reader to a Tierra 2011 document, and does not provide any discussion of the updated CSM. Given the importance of the CSM for guiding the BHHRA, the PFD should include a thorough summary of the human health CSM and its linkages to sources and migration pathways.	Additional detail pertaining to the CSM will be added to the PFD. The 2011 Tierra CSM document will be revised and submitted to EPA.
177.	Figure 5-1	Subtidal sediment is identified as a secondary source with linkage to fish and shellfish only. Direct contact with subtidal sediment is not included as a potential exposure route in the human health CSM. How is subtidal sediment defined and distinguished from intertidal sediment?	The subtidal and intertidal components of the CSM will be reviewed and further described in the PFD.
178.	Figure 5-1	Looking on Figure 5-1, it may appear to some that ingestion of fish/shellfish will be evaluated separately for each of the 3 media (i.e., subtidal sediment, intertidal sediment, and surface water). In other words, that there will be fish samples specifically collected in connection with the specific medium, which is not the case. Consider revising the CSM and using arrows instead of separate boxes for the ingestion of fish/shellfish exposure.	The CSM will be revised to address this comment.
179.	Section 5.2, Human Exposure Scenarios, Page 5-1.	The submission indicates that the COPC in NBSA environmental media are expected to decrease over time. The basis of this statement should be justified.	Information which supports the statement, that COPCs in NBSA environmental media are expected to decrease over time, will be added.
180.	Section 5.2, Human Exposure Scenarios, Page 5-1.	While the future land use of the Newark Bay may not change, restoration efforts will increase the frequency of use of this waterway for various recreational and sport related activities. A reasonable maximum exposure scenario for a combined current and future land use should consider results of the current and planned restoration efforts.	It will be emphasized that the RME scenario for a combined current/future land use will consider current and planned restoration efforts.

Comment No.	Section, Page No., Paragraph	Comment	Response
181.	Section 5.2, Human Exposure Scenarios, Page 5-1, second paragraph.	The "additional notable comments and guidance" text provided here seems out of place. In fact, information provided in the first bullet "USEPA's comments on the Interim CSM" is taken out of context and does not support what the main paragraph of Section 5.2 is stating. Suggest incorporating this text better with the main paragraph of this section or deleting it.	The noted language and bullet will be removed.
182.	Section 5.2, Human Exposure Scenarios, Page 5-2.	The second bullet on this page implies downgrading resource value or remedial goal and is considered both premature and inappropriate in this document. It should be removed from the report.	The second bullet will be removed.
183.	Section 5.3, Human Health Exposure Factors, Page 5-2.	This paragraph is too vague. Please state specifically the exposure factors that will be used from the LPRRP, and identify those that will require site-specific information.	As agreed-to during the 1/22/13 call with EPA, the exposure parameters will be specified in the PAR and do not need to be addressed in the revised PFD. They will be presented in RAGS Part D tables.
184.	Section 5.4, Potentially Exposed Human Populations.	Include additional information that indicates whether a flood plain has been identified or not within Newark Bay, including copies of FEMA maps.	While this specific comment was not discussed with EPA on the 1/22/13 call, consistent with responses to Comments #40, 187, 189 and 210, this comment will be addressed in a later document, rather than the revised PFD.
185.	Section 5.4.1, Recreational Users, Page 5-3.	In addition to the information provided, please note that the National Park Service (NPS) is actively developing a canoe and kayak trail down the Passaic River and into Newark Bay, concluding on Kearny Point with a boat ramp and possible picnic area. Although Appendix D provides a comprehensive list of references for recreational use information, please also check with the NPS.	The NPS will be contacted and any recreational information relevant to the Newark Bay assessment will be added.
186.	Section 5.4, Potentially Exposed Human Populations, Page 5-3.	As discussed in Section 6, further survey work is proposed for determining shoreline access throughout the NBSA. Current and future land use scenarios for consideration in the baseline HHRA should be revisited pending the outcome of that evaluation.	After additional site reconnaissance for "ground-truthing" (see Comment #210), land use assumptions will be re-evaluated.

Comment No.	Section, Page No., Paragraph	Comment	Response
187.	Section 5.4, Potentially Exposed Human Populations, Page 5-3.	The document should include a table summarizing the specific receptors, relevant age groups, and exposure pathways to be evaluated for each (such as Table 4-1 of the LPRSA PFD). Scenarios that are proposed for qualitative evaluation should be identified and justified.	As agreed-to during the 1/22/13 call with EPA, the exposure parameters will be specified in the PAR and do not need to be addressed in the revised PFD. They will be presented in RAGS Part D tables.
188.	Section 5.4.1, Recreational Users, Page 5-3.	Surveys and desktop evaluations performed to date have been subjective and are noted as preliminary. What additional surveys are planned? The discussion of the desktop evaluation of recreational uses of the NBSA references Appendix C as providing the list of entities contacted. This should be corrected to Appendix D.	This text will be clarified and the citation will be corrected from Appendix C to Appendix D.
189.	Section 5.4.1, Recreational Users, Page 5-3.	As described in Appendix D, the presence of marinas and kayak/canoe rental outfits in the Bay and Hackensack River should be noted. A map indicating the location of boat ramps, marinas, boat rental outfits would be helpful for identifying potential recreational points of exposure.	The locations of boat ramps, marinas, and boat rental outfits on Newark Bay will be researched and available information will be depicted. Tierra disagrees with the need for mapping recreational locations on the Hackensack River.
190.	Section 5.4.2, Commercial Users, Page 5-5.	Suggest matching up the term for commercial worker with that on the CSM figure (which uses "port/dock worker").	The text will be modified to use port/dock worker instead of commercial worker.
191.	Section 5.4.2, Commercial Users, Page 5-5.	The discussion regarding commercial divers requires further clarification regarding how the divers may be exposed to sediments and surface water. It is recommended that information be provided regarding the personal protective equipment, wet suits, etc. that are used in this type of diving and how it is anticipated that the diver may be exposed. It is also important to clarify how this information will be used in the risk management decision. A qualitative assessment in the Risk Characterization may be more appropriate than the proposed quantitative assessment.	The commercial diving scenario will be further researched, including the issue of whether divers in the area wear wet or dry suits. Clarification is needed as to whether EPA and the Partner Agencies are requesting that this scenario be assessed qualitatively or excluded. EPA makes risk management decisions, so any clarification regarding how this scenario will be used in risk management will need to come from EPA. Discussion of risk management seems out of place in the PFD.

Comment No.	Section, Page No., Paragraph	Comment	Response
192.	Section 5.4.3, Transient Users, Page 5-5.	The PFD notes that a comprehensive search for information was performed. One additional suggestion for obtaining region specific information is to interview local civic and church (and other non-profit organizations) which may provide services to this group and therefore have more definitive information on their presence in the study area.	As agreed-to during the 1/22/13 call with EPA, EPA will provide feedback regarding this comment.
193.	Section 5.4.3, Page 5-5	Suggest adding text that wraps up the discussion on the transient receptor by stating that it will be evaluated qualitatively, given the lack of information. EPA concurs that a qualitative discussion of transient individuals in the Risk Characterization would be appropriate.	Text will be added as suggested.
194.	Section 5.5, Human Health Exposure Pathways.	The difference between intertidal and subtidal sediments, as it relates to human exposure, needs to be defined. Both are listed as media of interest for the baseline HRRA, "to be assessed separately." Please differentiate which type of sediment exposure will be considered for each receptor. The data needs for intertidal sediment and surface water in Sections 5.6.2.2 and 5.6.2.3 indicate that data is needed from accessible areas. How will the determination of accessible intertidal sediments and surface water be made?	Subtidal and intertidal sediments will be defined and further discussed within the context of receptor exposures. An explanation will be added that describes how accessible areas will be determined.
195.	Section 5-5, Human Health Exposure Pathways, Page 5-8.	Please provide justification for only qualitatively evaluating inhalation of chemicals that volatilize and the exposures to the transient receptor. Also, note that the second bullet "Exposures to a transient population that potentially reside or spend considerable time along the shore" encompasses more than one pathway; therefore the lead-in sentence referring to "two" pathways is not correct. Suggest editing the sentence to state, "The following pathways/receptor scenarios will be assessed qualitatively."	Per USEPA's request at the June 2011 workshop, the inhalation pathway will be evaluated quantitatively, at least at a screening level, to address any public concern over volatiles. This information will be added to the inhalation bullet. The transient population will be evaluated qualitatively, for all pathways, due to lack of available information for this population. The recommended changes to the language regarding the transient receptor will be made.
196.	Section 5.5.1, Angler/Sportsman, Page 5-8.	The discussion of the exposures should use the terms RME and CTE, and not subsistence.	The subsistence term will be removed and it will be specified that RME/CTE scenarios will be evaluated.

Comment No.	Section, Page No., Paragraph	Comment	Response
197.	Section 5.5.1, Angler/Sportsman, Page 5-8.	Please confirm with EPA that soft-shell clams will be consumed and that both typical and a subsistence angler/sportsman scenarios will be evaluated as indicated in the text. If these clams will not be consumed please delete reference to them.	As agreed-to during the 1/22/13 call with EPA, the subsistence term will not be used and it will be specified that RME/CTE scenarios will be evaluated. Tierra will investigate whether soft shell clams will be consumed and modify the text accordingly.
198.	Sections 5.5.1 and 5.5.2, Page 5-8.	It is not clear why a boating scenario with anglers and crabbers is not being considered. Angling and crabbing is not limited to the shoreline.	A boating scenario is being included. The angler/crabber scenario includes contact with surface water and sediment. It is unclear how the exposures of anglers/crabbers in boats is quantitatively different from that of anglers/crabbers on the shore with the exception that individuals in boats will have less opportunity for contact with sediment. It will be clarified that the exposures of potential anglers/crabbers in boats is consistent with the angler/crabber scenario.
199.	Section 5.5.2, Recreational Users, Page 5-8.	Please indicate which sediment (e.g., intertidal, subtidal) will be evaluated for these receptors.	Subtidal and intertidal sediments will be defined and further discussed within the context of receptor exposures.
200.	Section 5.5.3, Port/Dock Worker, Page 5-8.	Please indicate which sediment (e.g., intertidal, subtidal) will be evaluated for these receptors.	Subtidal and intertidal sediments will be defined and further discussed within the context of receptor exposures.
201.	Section 5.6.1, Land Use, Page 5-9.	If duck hunting will be qualitatively discussed, please add it to the CSM, Figure 5-1.	The PFD will be revised to indicate that duck hunting is not occurring in Newark Bay.
202.	Section 5.6.2.1, Fish and Shellfish, Page 5-10.	The data needs for fish/crab tissue should be specific as to tissue types (e.g., fillet for fish, and muscle/hepatopancreas for crab etc.). In addition, a preliminary list of target species should be included. This information was included in the LPRSA PFD.	Specific fish/crab tissue types and data needs for these tissue types, as well as a list of target species will be included in the sampling work plan, therefore this level of detail is beyond the scope of the PFD.

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203.	Section 5.6.2.2, Intertidal Sediment Concentrations, Page 5-10.	The areas of intertidal exposures should also include consideration of human activity beyond areas where CSOs/SWOs are located.	Additional clarification will be added to this section.
204.	Section 5.6.2.2, Intertidal Sediment, Page 5-10.	This section refers to intertidal sediment; however both intertidal and subtidal sediment were identified as media of interest to be assessed separately in Section 5.5. Please add text describing where collection of subtidal sediment will occur, or discuss whether available subtidal sediment data are sufficient for the baseline HHRA.	Subtidal and intertidal sediments will be defined and further discussed within the context of receptor exposures. The need for, and locations of, sediment sampling will be described in sampling work plans and are outside the scope of the PFD.
205.	Section 5.6.3, Exposure Factors, Page 5-10.	Further evaluation of actual residential exposure to the NBSA and the potential for exposure to any transient populations should also be added as an objective in terms of what additional data is needed for the risk assessment.	Further evaluation of any actual residential exposure to the NBSA will be added as an objective. Depending on the feedback received from EPA regarding the need for additional research into transient populations (Comment #192), language may be included as needed.
206.	Section 5.6.3, Exposure Factors, Page 5-10.	Please identify which exposure factors require additional data gathering.	Additional detail will be added to this section.
207.	Section 5.6.3, Exposure Factors, Page 5-10.	No mention of cooking loss is included. Will cooking loss be included in the assessment of exposure from consumption of fish/crab? How will this physical process be addressed?	Cooking loss will be assessed, and a detailed discussion of such will be included in the PAR.
208.	Section 6, Next Steps.	Without knowing the outcome of the ongoing secondary data evaluations noted in Section 3, the data needs identified in Section 6 should be described as preliminary and subject to revision pending the outcome of these evaluations.	This language will be added.

Comment No.	Section, Page No., Paragraph	Comment	Response
209.	Section 6, Next Steps.	Section 6 indicates that a Risk Assessment and Risk Characterization (RARC) Work Plan will be developed. EPA's position is that such a report is not needed for the NBSA RI/FS. The EPA would like to go directly from the FSP and data collection to the risk assessments, as there is no need for intermediate documents/summaries or additional work plans on how the data will be used for the risk assessment. Tierra should instead provide more detailed information on specific ecological receptors, updated assessment endpoints, selected measurement endpoints, and data quality objectives in an introduction to the FSP or QAPP. Tierra should follow EPA guidance, use the data that was collected, and prepare the risk assessment reports (BERA and HERA). EPA would consider meeting with Tierra to discuss their assessment and characterization analysis approaches following data collection; such a meeting would potentially be helpful to speeding up the reporting and review process.	Tierra agrees that a RARC is not necessary and instead will prepare detailed sampling plans, collect analytical data, and prepare the BERA and BHHRA.
210.	Appendix B	The process of determining shoreline access relied on Google Earth imagery, ground-truthed by on-site reconnaissance when access was not clear from the imagery. Appendix B states that, "Most residentially zoned properties had fences, obstructions, or significant land elevation differences inhibiting direct contact with NBSA surface water and sediment." Were these "obstructions" visible simply relying on Google Earth imagery, or were they all ground-truthed? The shoreline type (i.e., rip rap, bulkhead, vegetated) should be included on a figure to further validate determinations regarding access to the shoreline. Will the proposed field survey/reconnaissance identified in Section 6 provide this information?	As agreed-to during the 1/22/13 call with EPA, ground-truthing Google Earth images by taking additional photos and documenting the shoreline type will be conducted during sampling. These assessments and findings will be included in later documents and do not need to be addressed in the revised PFD.